BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division
ARUN G. RAO
Deputy Assistant Attorney General
GUSTAV W. EYLER
Director
Consumer Protection Branch
ALLAN GORDUS
Assistant Director
NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-305-2428
noah.t.katzen@usdoj.gov

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BRAVO PACKING, INC., a corporation, and JOSEPH MEROLA and AMANDA LLOYD, individuals, Defendants.	Case No. 22-cv-1380

COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, on behalf of the United States Food and Drug Administration ("FDA"), by and through its undersigned attorney at the United States Department of Justice's Consumer Protection Branch, alleges:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to halt the manufacture and distribution of adulterated raw animal food products. FDA laboratory testing has revealed that Defendants' raw animal food is contaminated with the pathogen *Salmonella*, a health risk to animals and humans, and FDA inspections have shown that Defendants' manufacture their raw animal food under grossly insanitary conditions. Plaintiff seeks an injunction to restrain and enjoin Defendants from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of animal food that are adulterated: (1) within the meaning of 21 U.S.C. § 342(a)(1) in that they bear or contain a poisonous or deleterious substance, namely *Salmonella*, which may render them injurious to health, and (2) within the meaning of 21 U.S.C. § 342(a)(4), because they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health;

B. Violating 21 U.S.C. § 331(k), by causing articles of animal food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391.

THE PARTIES

4. Plaintiff, the United States of America, brings this action on behalf of FDA, the agency mandated to protect the public health.

5. Defendant Bravo Packing, Inc. ("Bravo") is a corporation located at 59 N. Golfwood Ave., Carneys Point, New Jersey 08069, within the jurisdiction of this Court.

6. Defendant Joseph Merola is the Owner and Secretary of Bravo. He has the duty, power, and authority to prevent, detect, and correct violations and hire and fire employees. He is responsible for recipe adjustments and maintains financial oversight over all purchases and equipment repair. Joseph Merola performs his duties at the Bravo facility, within the jurisdiction of this Court.

7. Defendant Amanda Lloyd is the President of Bravo. Her primary responsibilities include managing product orders, ordering supplies, and overseeing accounting duties. She maintains Bravo's receiving and shipping records. Ms. Lloyd performs her duties at the Bravo facility, within the jurisdiction of this Court.

DEFENDANTS' PRODUCTS

8. Defendants manufacture, process, prepare, pack, hold, and distribute articles of food within the meaning of 21 U.S.C. § 321(f), namely raw animal food products.

9. Bravo manufactures raw animal food products at its Carneys Point facility. Bravo's animal food products include raw dog food and raw food for large exotic cats such as lions, tigers, and panthers.

10. For their raw animal food products, Defendants grind their own beef, tripe, and trachea from cows that they slaughter on site. The ground beef, tripe, and trachea are then extruded into a mixer, where they are combined with other ingredients, including dehydrated egg

powder and salted blood. The food is packaged in plastic bags, which are frozen before distribution.

11. Defendants distribute their raw animal food products in interstate commerce to customers located in New York.

12. Defendants receive a mineral mix used in their raw animal food products in interstate commerce from a supplier in Pennsylvania.

HEALTH RISKS ASSOCIATED WITH DEFENDANTS' PRODUCTS

13. Defendants' raw animal food products have continuously been found to contain the pathogen *Salmonella,* which is a health risk to humans and animals. Because Defendants' products are not intended to be cooked or subject to another type of preparation that would destroy any pathogens before being served to animals, the *Salmonella* in the raw animal food presents a significant public health risk to both animals and humans who handle the food and care for the animals. *Salmonella* can cause illness, called salmonellosis, in both humans and animals, and it is easily transferred from animal food to humans through handling, or from infected animals to humans.

14. Salmonellosis in humans is typically associated with diarrhea, fever, and abdominal cramps that lasts 4 to 7 days. Although the symptoms usually resolve without treatment in healthy adults, salmonellosis can cause severe dehydration and lead to death without prompt treatment in certain populations, including infants, young children, the elderly, transplant recipients, pregnant women, and individuals with weakened immune systems. A small number of individuals with *Salmonella* infections develop reactive arthritis (i.e., arthritis from an immune reaction to the infection), which can lead to chronic arthritis. The Centers for Disease

Control and Prevention ("CDC") estimate that annually there are 1.35 million human cases of salmonellosis in the United States, with 26,500 hospitalizations and 420 deaths.

15. Humans can become infected with *Salmonella* if they touch contaminated animal food and do not thoroughly wash their hands afterward. In addition, *Salmonella* in animal food can cross-contaminate human food if the animal food is stored or handled in common areas with human food, a regular practice among consumers.

16. Dogs infected with *Salmonella* from contaminated animal food can exhibit symptoms such as vomiting, diarrhea, fever, loss of appetite, and/or decreased activity level. In some cases, the *Salmonella* infection may spread from the animal's intestines to the blood stream, leading to death if not treated. However, infected dogs often do not appear to be sick after consuming food contaminated with *Salmonella*, but can still be carriers of *Salmonella* and spread the pathogen to their human owners.

17. Any infected animal will shed *Salmonella* in its feces, and *Salmonella* can be transmitted to humans if they do not thoroughly wash their hands after cleaning up animal feces. Additionally, many animals groom themselves after they eat or defecate, and *Salmonella* can be transmitted from their mouths to surfaces that they subsequently lick, including a person's face or hands. For example, if a pet plays with a toy immediately after eating food containing *Salmonella*, the pathogen could easily transfer to people who touch the toy and then their mouths; this scenario is very common with young children.

REGULATORY FRAMEWORK

18. Defendants' raw animal food products are animal food within the meaning of the Act, 21 U.S.C. § 321(f).

19. Animal food is adulterated if it bears or contain a poisonous or deleterious substance, such as *Salmonella,* which may render the animal food injurious to health. 21 U.S.C. § 342(a)(1).

20. Animal food manufacturers, like Defendants, that manufacture, process, pack, or hold food for consumption in the United States, and for which an exemption under 21 C.F.R. § 1.226 does not apply, are required to register their facility with FDA under 21 U.S.C. § 350d. Registered animal food manufacturers are subject to FDA's current good manufacturing practice ("CGMP") regulations for animal food, which establish basic practices that must be followed, and conditions that must be maintained, to ensure that animal food is processed in a safe and sanitary manner. *See* 21 C.F.R. Part 507. The exemptions from registration for food manufacturing facilities under 21 C.F.R. § 1.226 include foreign facilities, farms, retail food establishments, restaurants, non-profit food establishments, fishing vessels, and facilities that are regulated exclusively by the United States Department of Agriculture. None of the exemptions in 21 C.F.R. § 1.226 apply to Defendants' facility.

21. Registered animal food manufacturers must monitor, with sufficient frequency, their sanitation conditions and practices used during processing to ensure, at a minimum, that they conform with the CGMP regulations for manufacturing, processing, packing, or holding animal food. *See, e.g.*, 21 C.F.R. Part 507 subpart B; 21 C.F.R. § 507.5(a). Violations of CGMP help to determine whether the facilities, methods, practices, and controls used to process animal food are sanitary and safe. 21 C.F.R. § 507.1(a)(1)(ii); *see also* 21 C.F.R. Part 507.

22. Failure to follow the animal food CGMP regulations renders the animal food adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 507.1(a)(1)(ii).

DEFENDANTS' VIOLATIONS

23. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, animal food that is adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4).

24. Defendants violate 21 U.S.C. § 331(k) because they cause animal food held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4).

25. Defendants' animal food products are adulterated within the meaning of 21 U.S.C. § 342(a)(1) in that they bear or contain a poisonous or deleterious substance, namely *Salmonella,* which may render them injurious to health.

26. Defendants' animal food products are adulterated within the meaning of 21 U.S.C. § 342(a)(4), because they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

27. Defendants are required to register their facility because it manufactures, processes, packs, or holds food for consumption in the United States and an exemption under 21 C.F.R. § 1.226 does not apply. *See* 21 U.S.C. § 350d; 21 C.F.R. § 1.225. Facilities that are required to register pursuant to 21 C.F.R. § 1.225 must comply with the CGMP requirements of 21 C.F.R. Part 507. *See* 21 C.F.R. § 507.5(a). Defendants have registered their facility for the period 12/07/2020 - 12/31/2022. Because Defendants process animal food products without adhering to the CGMP regulations, the products are adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 507.1(a)(1)(ii).

EVIDENCE OF VIOLATIONS

28. Defendants have had multiple instances of positive *Salmonella* findings in samples taken by FDA of finished raw animal food products. In addition, Defendants have an extensive history of manufacturing raw animal food products under grossly insanitary conditions. Defendants' insanitary conditions can result in *Salmonella* being transferred from one lot of raw animal food to another. For example, one lot of raw animal food can be cross-contaminated by *Salmonella* from another lot through insanitary processing equipment and from personnel that do not follow proper hygiene. *Salmonella* can also be introduced into the raw animal food from pests such as cats and mice that can access food processing areas. Defendants' pattern of continuing violative conduct has been documented by FDA investigators during inspections on May 25- 28, 2021 (the "May 2021 inspection"); January 21, 2021 to April 7, 2021 (the "April 2021 inspection"); and July 22, 2019 to August 6, 2019 (the "July 2019 inspection").

Presence of Pathogens at Recent Inspections

29. Although FDA observed serious violations of CGMP at all inspections, as discussed below, FDA samples taken at the April 2021 and July 2019 inspections further revealed the presence of pathogens in Defendants' finished raw pet food products and Defendants' facility.

30. FDA conducted the April 2021 inspection in response to a consumer complaint received by FDA on December 10, 2020, in which a non-profit group collected a sample of Defendants' raw animal food product from a retailer in California and discovered *Salmonella* in the sample through private laboratory testing,

31. FDA investigators collected multiple finished raw pet food product samples during the April 2021 inspection.

32. Subsequent testing by FDA revealed the presence of *Salmonella* in two out of three finished raw pet food product samples from the April 2021 inspection.

33. FDA investigators also collected finished raw animal food product samples at the July 2019 inspection.

34. Subsequent testing by FDA revealed the presence of *Salmonella* in 2 out of 2 finished raw pet food product samples from the July 2019 inspection.

35. FDA investigators also collected environmental samples from the food processing areas of Defendants' facility during the April 2021 inspection. Subsequent testing of the environmental samples by FDA revealed the presence of *Listeria monocytogenes* ("*L. mono*").

36. FDA testing also found *L. mono* in three out of three of the finished raw pet food product samples from the April 2021 inspection.

37. Subsequent testing also revealed the presence of *L. mono* in 1 out of 2 finished raw pet food product samples from the July 2019 inspection.

38. To determine whether insanitary conditions at Defendants' facility facilitated the harborage of a strain of *L. mono*, FDA performed whole genome sequencing ("WGS") analysis on the April 2021 and July 2019 inspectional samples. FDA uses WGS to determine the complete and unique DNA make-up of an organism which can reveal pathogens with matching genomic sequence profiles originating from the same source. WGS of the samples from April 2021 and July 2019 showed that a resident strain of *L. mono* has been established in Defendants' facility.

39. The presence of such a strain of *L. mono* is evidence that Defendants have failed to maintain a clean and sanitized facility and have created an ideal environment for dangerous pathogens to contaminate their raw animal food products.

CGMP Violations at the Most Recent Inspection

40. FDA conducted its most recent inspection in May 2021. The purpose of the May 2021 inspection was to confirm that the Defendants implemented the corrective actions that they committed to make after the April 2021 inspection.

41. During the May 2021 inspection, FDA investigators observed numerous deviations from the animal food CGMP regulations that were the same or similar to violations observed at previous inspections, including, but not limited to, the following:

A. Defendants failed to maintain the buildings, structures, fixtures, and other physical facilities of their plant in a clean manner and in good repair to prevent animal food from becoming adulterated, in violation of 21 C.F.R. § 507.19(a). For example, as they did at the previous inspection in April 2021, the investigators observed deep depressions, holes, and cracks, all of which contained pools of bloody water, in the floors of all food processing areas, including the slaughter room, deboning room, processing room, deboning room cooler, and raw ingredient cooler. Bacteria thrive in moist areas such as pools of blood or water, increasing the risk for product contamination. In addition, FDA investigators observed that Defendants stored uncovered barrels of deboned meat, an ingredient in their raw animal food, directly beneath a metal beam and brackets covered with flaking rust.

B. Defendants failed to ensure that animal food-contact and non-contact surfaces of utensils and equipment are cleaned and maintained and utensils and equipment stored as necessary to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, in violation of 21 C.F.R. § 507.19(b). In addition, they failed to ensure that animal food-contact surfaces are cleaned and sanitized before use, in violation of 21 C.F.R. § 507.19(b)(2). For example, FDA investigators observed that Defendants did not

remove debris that had adhered to production equipment used in the deboning, grinding, mixing, in-process holding, and bagging operations for raw animal food. Instead, Defendants sprayed a sanitizer, which was not labeled to control all pathogens previously identified in the product and environment, including *L. mono,* onto the debris covered equipment. In addition, FDA investigators observed that Defendants did not clean the mixer prior to the production of ready-to-eat raw dog food. The mixer contained an unknown substance of pooled black liquid and white fat-like deposits along the bottom of its basin;

C. Defendants failed to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests, in violation of 21 C.F.R. § 507.19(e). For example, FDA investigators observed cats sitting and urinating on uncovered barrels containing deboned meat that Defendants stored outside. Defendants subsequently used this deboned meat to produce raw dog food. In addition, despite Defendants' claims following the April 2021 inspection that they would repair doors that cats used to enter the facility, FDA investigators saw multiple cats entering and exiting the deboning room through an open sliding door; and

D. Defendants failed to take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food, in violation of 21 C.F.R. § 507.14(a). For example, FDA investigators observed Defendant Merola repeatedly spitting on the floor of the food processing area, a practice he had committed to ending during the April 2021 inspection. Additionally, although the Defendants installed a sanitizing footbath after the April 2021

inspection, FDA investigators at the May 2021 inspection observed that the footbath was either not being used or being used incorrectly.

CGMP Violations at Previous Inspections

42. FDA investigators observed significant ongoing violations of the Act and the animal food CGMP requirements during the April 2021 and July 2019 inspections, and issued Forms FDA-483 at the conclusion of the inspections. The Form FDA-483s for both inspections included observations of the same types of deficiencies observed at the May 2021 inspection.

43. At both previous inspections, FDA investigators observed numerous deviations from the animal food CGMP including, but not limited to, the following:

A. Defendants failed to ensure all animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food, in violation of 21 C.F.R. § 507.25(a)(8). For example, as discussed above, the numerous positive samples for *Salmonella* and *L. mono* collected from Bravo's manufacturing environment and finished product samples during the April 2021 and July 2019 inspections strongly indicated that Bravo's conditions and controls to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food were highly ineffective;

B. Defendants failed to maintain their plant in a clean manner and in good repair to prevent animal food from becoming adulterated, in violation of 21 C.F.R. § 507.19(a). For example, at the April 2021 inspection, FDA investigators observed a mix of pooled blood and water in the depressions, holes, and cracks in the floors throughout the food processing areas. FDA investigators also observed employees dragging barrels containing raw ingredients

across the blood-soaked floors in the raw ingredient cooler. In addition, at the July 2019 inspection, FDA investigators observed condensate drip and ice buildup on cases of the finished raw animal food product in one of the freezers;

C. Defendants failed to ensure that animal food-contact and non-contact surfaces of utensils and equipment are cleaned and maintained and utensils and equipment stored as necessary to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, in violation of 21 C.F.R. § 507.19(b). In addition, they failed to ensure that animal food-contact surfaces are cleaned and sanitized before use, in violation of 21 C.F.R. § 507.19(b)(2). For example, during the April 2021 inspection, FDA investigators observed that Defendants did not clean or sanitize primary manufacturing areas, such as the deboning room and production rooms. In addition, as they did at the May 2021 inspection, FDA investigators observed that Defendants did not clean the product residue from equipment before processing food. Also, storage barrels that were purportedly "cleaned and sterilized" were found to contain diluted blood or other pooled liquid and remnants of meat. Similarly, during the July 2019 inspection, FDA investigators observed several raw ingredient barrels containing black residue and pooled sanitizer after the Defendants cleaned the barrels; and

D. Defendants failed to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests, in violation of 21 C.F.R. § 507.19(e). For example, FDA investigators observed multiple cats entering and leaving the deboning room at the April 2021 inspection. FDA investigators also observed cat feces in a corner of the deboning room. Defendant Merola stated that he cannot prevent the cats from entering the building. During the July 2019

inspection, FDA investigators observed similar evidence of mice on cardboard boxes in a storage area; and

E. Defendants failed to take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food, in violation of 21 C.F.R. § 507.14(a). For example, during the April 2021 inspection, FDA investigators observed employees stepping on manufacturing equipment food-contact surfaces while wearing boots that had not been cleaned or sanitized after leaving the food processing area. FDA investigators also observed Defendant Merola spitting chewing tobacco on the production floor, and an employee return from a toilet and smoke break without washing her hands before filling plastic bags with finished dog food.

HISTORY

44. Defendants have received ample notice that their manufacture of raw animal food violates the law and that continued violations could lead to regulatory action. At the close of the May 2021, April 2021, and July 2019 inspections, FDA investigators issued Forms FDA-483 to Defendants that notified them of the investigators' observations. FDA investigators also discussed their observations with Defendants and encouraged them to make necessary corrections.

45. In addition, following the July 2019 inspection, FDA sent Defendants a Warning Letter dated March 16, 2020, that detailed their CGMP violations.

46. In response to the inspections and the Warning Letter, the Defendants have repeatedly promised, both orally and in letters to FDA, to bring their facility into compliance with regulatory requirements.

47. Defendants are also aware of the danger that *Salmonella* contamination poses, as they have conducted voluntary full product recalls of their raw pet food products following the findings of *Salmonella* in their finished product samples in September 2019 and twice in March 2021.

50. Defendants have failed, however, to correct the insanitary conditions at their facility that have led directly to the *Salmonella* contamination in their finished products.

51. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, cease manufacturing, processing, preparing, packing, holding, or distributing articles of animal food, unless and until Defendants' facilities, methods, processes, and controls used to manufacture, process, prepare, pack, hold, and distribute articles of animal food are established, operated, and administered in conformity with the Act and applicable regulations, in a manner acceptable to FDA; and

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, be restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

a. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce

articles of animal food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4) ; and

b. Violating 21 U.S.C. § 331(k), by causing articles of animal food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342 (a)(1) and (a)(4); and

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the manufacture, processing, preparing, packing, holding, and distribution of Defendants' products to ensure continuing compliance with the terms of the injunction, and that the Defendants bear the costs of such inspections at the rates prevailing at the time of the inspection(s) are accomplished; and

IV. Award Plaintiff costs incurred in pursuing this action, including the costs of investigation to date; and

V. Order such other and further equitable relief as this Court deems just and proper.

Dated this 15th day of March, 2022.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

ALLAN GORDUS
Assistant Director

/s/ Noah T. Katzen
NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-305-2428
noah.t.katzen@usdoj.gov

OF COUNSEL:
DANIEL J. BARRY
Acting General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation

TARA BOLAND
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration

DESIGNATION OF AGENT FOR SERVICE

Pursuant to Local Rule 101.1(f), because the Department of Justice's Consumer Protection Branch does not have an office in this district, the United States Attorney for the District of New Jersey is hereby designated as an alternative to undersigned counsel to receive service of all notices or papers in the captioned matter. Therefore, service upon the United States Attorney's Office or its authorized designee:

David E. Dauenheimer
Deputy Chief, Government Fraud Unit
United States Attorney's Office
District of New Jersey
970 Broad Street, Suite 700
Newark, NJ 07102-2534

shall constitute service upon the United States for purposes of this action.

Dated: March 15, 2022

/s/ Noah T. Katzen

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-305-2428
noah.t.katzen@usdoj.gov